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**SAFETY AND EFFICACY OF UNWASHED FILTERED WOUND
DRAINAGE BLOOD REINFUSED FOLLOWING ORTHOPAEDIC
SURGERY**

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Safety and Efficacy of Unwashed Filtered Wound Drainage Blood Reinfused Following Orthopaedic Surgery

Autologous blood products are being used increasingly to fulfill the needs of patients undergoing orthopaedic and other surgical procedures. The major impetus for this practice is the concern about potential risks associated with homologous blood, e.g. the transmission of blood-borne infectious agents such as human immunodeficiency virus (HIV) and hepatitis viruses.

Autologous blood collected prior to surgery and shed blood collected intraoperatively and postoperatively are being used in place of homologous blood.^{1,2,3} Shed blood from orthopaedic wounds may be contaminated with fat particles, bone fragments, and methylmethacrylate monomer. Shed blood may also contain increased levels of plasma hemoglobin and fibrin degradation products as a result of hemolysis and clot lysis, and orthopaedic shed blood may also contain products of platelet and complement activation.^{1,2,3} Although shed blood is filtered before reinfusion, there are opposing views on whether or not washing is necessary.

This randomized, prospective clinical trial in 128 patients was undertaken to evaluate shed blood recovered after hip or knee replacement, or spinal fusion surgery. The effects of the reinfusion of shed blood collected

postoperatively by two autotransfusion systems were compared with the effects of the transfusion of liquid preserved autologous and homologous blood.

MATERIALS AND METHODS

One-hundred twenty-eight orthopaedic patients at four medical centers were randomized for study. Surgical procedures included total knee replacement, total hip replacement or spinal fusion. Written informed consent was obtained from each study subject. This was a randomized study of a) patients in whom shed blood was collected using one of two wound drainage systems, the Orth-evacTM or the Solcotrans^R, and reinfused postoperatively using the Pall 40 micron screen filter or the Pall RC100 polyester filter, and b) patients who did not receive shed blood but received autologous or homologous liquid preserved red blood cells. The patients who did not receive shed blood were treated with a standard wound drainage system (hemovac) and received homologous or autologous liquid preserved red blood cells.

Drainage catheters were placed in each patient using conventional surgical methods according to the manufacturer's directions. With the Solcotrans drainage system, forty (40) ml of acid citrate dextrose (ACD, NIH Formula A) was used; no anticoagulant was added with the Orth-evac drainage system.

Patients treated with the Orth-evac or Solcotrans were reinfused with at least 250 mls of shed blood within six hours after initiation of collection. The standards and

hospital policies of the American Association of Blood Banks (AABB) were observed for all transfusions. The need for transfusion of autologous or homologous liquid preserved red blood cells was determined by the clinical condition of the patient as assessed by the attending physician. In instances where less than 250 mls of shed blood was collected or a transfusion was not required, the patient was dropped from the study.

Blood samples were taken from the patient and from the collection device at various stages of the study to determine the patient's hematologic status, the characteristics of the blood in the collection chamber, and the effects of filtering on the blood. The following samples were collected from each patient: (1) baseline venous samples were drawn from patients prior to surgery (pre-surgery); (2) venous samples were drawn from patients prior to transfusion (post-surgery, pre-transfusion); (3) samples of shed blood were taken from the collection chamber and samples of autologous and homologous blood were collected from the blood bag prior to and following filtration; (4) venous blood samples were drawn from patients one and 24 hours post-transfusion. Samples were drawn into K3EDTA, NaCitrate and FDP tubes and were evaluated as follows: In the K3EDTA samples, plasma hemoglobin, complement C3a dys arg, hemoglobin, hematocrit, red blood cell count, white blood cell count, platelet count

and fat content were measured;^{4,5,6} In the NaCitrate samples, fibrinogen, plasminogen, antithrombin III, prothrombin time, partial thromboplastin time, thrombin time, Factor V, Factor VIII, D-dimers, antiplasmin, plasmin and thrombin were measured; and in FDP samples, fibrin degradation products were measured.⁷⁻¹²

In 24 patients at one medical center, methylmethacrylate was measured in the shed blood five minutes after insertion of the knee prosthesis and in the patient one hour and 24 hours after reinfusion of the shed blood.^{13,14} All patients were closely monitored through measurements of blood pressure, heart rate, respiration rate, and temperature, after surgery and after reinfusion of the shed blood. Any adverse reactions or complications were recorded.

DATA ANALYSIS: The means and standard deviations are reported. T-tests were used to compare data collected on the patients who received shed blood and the patients who received autologous and homologous liquid preserved red blood cells. Comparisons of data collected prior to and following the reinfusion of shed postoperative drainage were made using analysis of variance.¹⁵

RESULTS

All the patients in the study were of similar age, height, weight, and sex (Table 1), and types of surgical procedures to which the patients were subjected were similar (Table 2).

Nine of 84 patients from whom shed blood was collected were not reinfused and were excluded from the study: eight patients because the drainage collected was less than 250 ml, and one patient because the shed blood was stored at room temperature for longer than 6 hours.

The last 50 ml of shed blood collected was not reinfused because this portion of the shed blood is known to contain fat particles.

The patients who received 338 ml of shed blood collected in the Orth-evac system and the patients who received 336 ml of shed blood collected in the Solcotrans system also received autologous and homologous liquid-preserved red blood cells (Table 3, 4). Figure 1 reports the total volume of shed blood collected from each patient in the study.

Of 35 patients who received no shed blood, seven (7) were transfused with homologous liquid preserved blood and

eight (8) received both homologous and autologous red blood cells (Table 4). Six (6) of 54 patients (11%) who received shed blood postoperatively also were transfused with autologous and homologous liquid preserved red blood cells. Eight of 35 patients (22%) who did not receive shed blood were transfused with autologous and homologous liquid preserved red blood cells. The relative risk of transfusion with homologous blood was 0.4 in the patients who received shed blood group compared to patients who did not receive shed blood. The reinfusion of shed blood reduced the requirement for homologous blood by 60%. However, this reduction was not statistically significant ($p=0.14$) as measured by chi-square.

Studies of Blood Collected in the Transfusion Systems

Hematocrit (HCT), hemoglobin (HGB), and red blood cell counts (RBC) were lower in the post-operative shed blood than in the autologous and homologous liquid preserved red blood cells (Table 5). Platelet counts were somewhat lower in the shed blood than in the autologous or homologous liquid preserved red blood cells. Plasma hemoglobin levels were similar in shed blood samples collected in the Orth-evacTM and the Solcotrans^R. The plasma hemoglobin level was lower in the postoperative shed blood than in the liquid stored red blood cells (Table 5).

Fibrinogen and antiplasmin levels were lower and Factor VIII and thrombin levels higher in the shed blood than in the autologous or homologous liquid preserved red blood cells (Table 5). Factor V levels were similar in shed blood and liquid preserved red blood cells (Table 5). Shed blood exhibited higher prothrombin times (PT) and thrombin times (TT) than the autologous or homologous liquid preserved red blood cells, but partial thromboplastin times (PTT) were similar (Table 5).

Plasminogen and plasmin levels were slightly higher in the shed blood than in the liquid preserved red blood cells (Table 5), but antithrombin III levels were similar (Table 5). Fibrin degradation products (FDP) and D-dimers were higher in the shed blood than in the liquid preserved red blood cells (Table 5). The shed blood exhibited higher concentrations of complement C3a dys arg (C3a) than the liquid preserved red blood cells (Table 5). Methylmethacrylate monomer (MMA) was not detectable in the shed blood samples tested.

Greater concentration of fat particles (both <10 um diameter and 10-40 um diameter) were seen in the shed blood than in the liquid preserved red blood cells (Table 5). The RC100 filter appeared to be more effective than the 40 micron filter in removing fat particles and white blood cells (Table 6). The quality of the shed blood was not

significantly different whether it was filtered through the 40 micron Pall filter or the Pall RC100 polyester filter except for a lower concentration of fat particles and white blood cells in shed blood filtered through the RC100 polyester filter.

Systemic Blood Studies

Systemic blood samples collected before surgery and at three points post-operatively revealed changes in hematologic parameters following surgery in all the patients studied whether they received shed blood or liquid preserved red blood cells mild reductions in hemoglobin concentrations and hematocrit values and increases in white blood cell counts were observed following surgery, and platelet counts were reduced for as long as 24 hours after transfusion.

At various post-surgical time points after the transfusion of the liquid preserved red blood cells, the level of fibrin degradation products (FDP) was roughly double that seen prior to surgery. In the patients who received the shed blood FDP was significantly increased one hour after transfusion to a level ten-fold that seen prior to surgery, but by 24 hours posttransfusion the levels were similar to those in the patients who received liquid preserved red blood cells (Table 7). D-dimer levels, which

also were increased at all post-surgical measurement times, were 3 to 4 times greater an hour after transfusion in the patients who received the shed blood than in the patients who received liquid preserved red blood cells, but similar 24 hours post-transfusion.

Fibrinogen levels were mildly to moderately decreased during surgery but within normal limits within 24 hours after transfusion of shed blood or liquid preserved red blood cells. Factor V, plasminogen, and antithrombin III levels were decreased within 24 hours after the transfusion of shed blood or liquid preserved red blood cells, but none of the other plasma proteins tested, including plasma hemoglobin, Factor VIII, antiplasmin, thrombin, plasmin, and complement C3a dys arg (C3a), showed any significant change, nor did prothrombin time (PT), partial thromboplastin time (PTT) or thrombin time (TT) (Table 7).

Methylmethacrylate monomer (MMA) was not detectable at any of the post-surgical time points (Table 7). In systemic blood samples, the levels of fat particles of both sizes (less than 10 um diameter (Fat <10) and between 10 and 40 um diameter (Fat 10-40)), were similar in the patients who received shed blood and those who received liquid preserved red blood cells (Table 7).

DISCUSSION

Our data indicate that reinfused unwashed orthopaedic wound drainage can be used safely and effectively in place of autologous or homologous liquid preserved red blood cells. When nonwashed, filtered shed blood was reinfused within six hours of collection, no febrile episodes or other transfusion reactions were observed.

Shed blood collected postoperatively using an autotransfusion device exhibited a lower hematocrit than autologous or homologous liquid preserved red blood cells. The shed blood had higher levels of activated complement C3a dys arg and prolonged prothrombin and thrombin time. Fibrin degradation products and D-dimers were significantly higher in the shed blood than in the liquid preserved red blood cells.

The decreases in fibrinogen and antiplasmin activity seen in the shed blood presumably were the result of clotting and lysis in the wound environment. The elevated thrombin level in the shed blood was probably due to conversion from prothrombin during the coagulation cascade. Factor VIII levels were also increased in shed blood.

The RC100 filter, designed to remove leukocytes, was more effective than the 40 um filter in removing both fat

particles and leukocytes from shed nonwashed blood. Neither filter affected any of the other measurements in shed blood.

The results of systemic blood studies were not significantly different between the patients who received liquid preserved red blood cells and those reinfused with shed blood collected with either Orth-evac or Solcotrans system. This may have been due in part to the fact that only 350 ml of shed blood were reinfused. The main differences seen between the two patient groups were higher levels of fibrin degradation products and D-dimers in the patients who received the shed blood. Results of coagulation studies were similar in the two groups of patients. Neither methylmethacrylate monomer nor elevated fat particles were seen in systemic blood samples from either group, in spite of the fact that the shed blood was not washed before reinfusion.

The reinfusion of orthopaedic wound drainage has been steadily gaining acceptance. The reinfusion of wound drainage after elective knee arthroplasty reduced the demand for homologous banked blood by two-thirds.¹⁶ Patients reinfused with shed blood following cardiac surgery required only half as much homologous blood as patients who did not receive shed blood.¹⁷ Several investigators have reported on the successful use of reinfused shed blood following

cardiac surgery, with no evidence of septic, pulmonary, hepatic, or renal complication.18,19,20,21,22

Our study reported here demonstrates that the reinfusion of unwashed filtered postoperative drainage from orthopaedic wounds is an acceptable alternative to the transfusion of liquid preserved red blood cells. The volume of shed blood collected in the orthopaedic setting was about 350 ml, and no untoward effects on hemostasis were observed following reinfusion.

TOTAL VOLUME OF DRAINAGE COLLECTED (ml)
(Thousands)

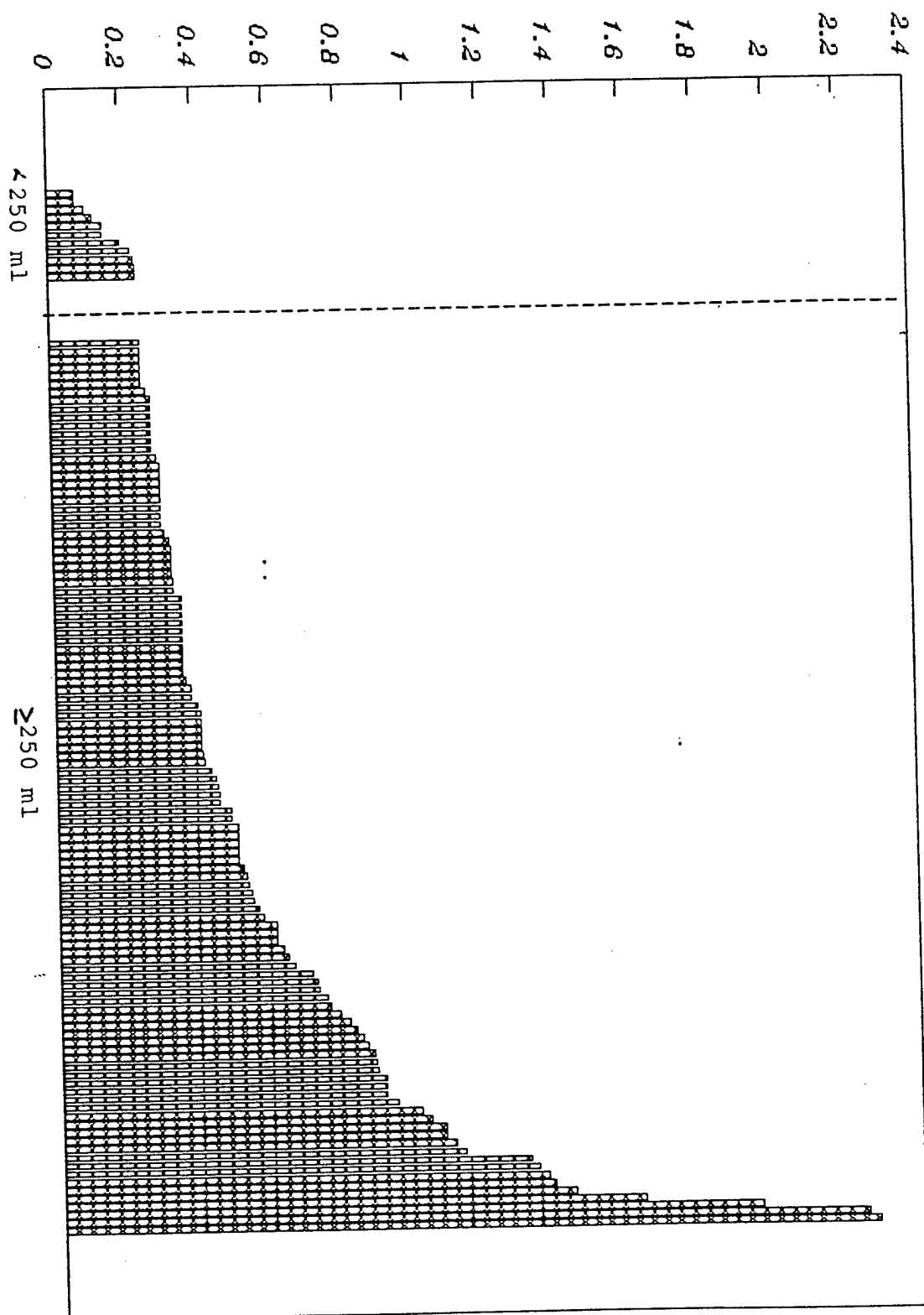


FIGURE 1
THE TOTAL VOLUME OF BLOOD COLLECTED FROM EACH PATIENT IN THE STUDY

TABLE 1

DEMOGRAPHIC DATA

	<u>ORTH-EVAC</u>	<u>SOLCOTRANS</u>	<u>CONTROL</u>
Number of Patients	44	40	44
Mean Age	67.9	66.3	62.5
Range	41-82	54-82	
Mean Height (in.)	65.7	67.2	67.3
Range	58-72	59-73.5	
Mean Weight (lb.)	178.2	190.7	190.4
Range	109.5-276	104.5-260	
Sex M	18	20	23
F	26	20	21

TABLE 2
SURGICAL PROCEDURES

	<u>ORTH-EVAC</u>	<u>SOLCOTRANS</u>	<u>CONTROL</u>
Total Knee	16	14	19
Bilateral Knees	16	10	7
Revision Knees	3	3	1
Total Hip	5	9	10
Revision Hips	4	3	7
Spine	0	1	0
TOTAL	44	40	44
Cemented	37	34	36
Uncemented	7	6	7
Cement Information Not Available	0	0	1

TABLE 3

VOLUME OF SHED BLOOD COLLECTED AND REINFUSED

<u>GROUP</u>	<u>SOLCOTRANS GROUP</u>	<u>ORTH-EVAC</u>
Volume Collected (ml)		
Mean:	401	466
SD:	219	276
n:	44	40
Range:	75- 930	125- 1370
Volume Reinfused (ml)		
Mean:	338	366
SD:	146	201
n:	36	39
Range:	175- 750	200- 900

TABLE 4

THE NUMBER OF UNITS OF AUTOLOGOUS AND HOMOLOGOUS LIQUID PRESERVED
BLOOD THAT WERE COLLECTED AND TRANSFUSED INTO THE 3 DIFFERENT
GROUPS OF PATIENTS

GROUP:	ORTH-EVAC	SOLCOTRANS	LIQUID PRESERVED
TOTAL # OF PATIENTS	36	39	43
TOTAL # OF PATIENTS PRE-DONATING BLOOD	26	28	35
# OF PREDONATED UNITS COLLECTED	60	80	92
% OF GROUP PREDONATING	72	72	81
# OF PATIENTS RECEIVING PREDONATED BLOOD	22	24	30
# OF PREDONATED UNITS TRANSFUSED	47	58	70
% OF GROUP RECEIVING PREDONATED BLOOD	61	62	70
% OF PATIENTS WHO PREDONATED RECEIVING PREDONATED BLOOD	85	86	86
# OF PATIENTS RECEIVING HOMOLOGOUS BLOOD	5	9	15
# OF HOMOLOGOUS UNITS TRANSFUSED	10	21	36
% OF GROUP RECEIVING HOMOLOGOUS BLOOD	14	23	34
# OF PATIENTS RECEIVING BOTH PREDONATED AND HOMOLOGOUS BLOOD	3	3	8
% OF GROUP RECEIVING BOTH PREDONATED BLOOD AND HOMOLOGOUS BLOOD	8	8	19

TABLE 5

IN VITRO MEASUREMENTS OF POSTOPERATIVE ORTHOPEDIC
DRAINAGE COLLECTED IN THE 2 RESERVOIRS AND LIQUID
PRESERVED BLOOD BEFORE FILTRATION

COLLECTION RESERVOIR:	POSTOPERATIVE DRAINAGE		ANOVA* "p"	LIQUID	SHED VS LIQUID
	ORTH-EVAC	SOLCOTRANS		PRESERVED BLOOD	PAIRED t-TEST "p"
<u>HEMATOCRIT (V%)</u>					
MEAN+SD	18+7	20+5	NS	52+27	<.0001
N	8	9		7	
<u>HEMOGLOBIN (gm/dl)</u>					
MEAN+SD	6.0+2.4	6.7+1.6	NS	16.5+8.5	<.0001
N	8	9		7	
<u>RED BLOOD CELL COUNT (x109/mm3)</u>					
MEAN+SD	2.04+0.73	2.10+0.60	NS	5.4+2.7	<.0001
N	8	9		7	
<u>WHITE BLOOD CELL COUNT (x103/mm3)</u>					
MEAN+SD	6.2+3.1	6.8+1.5	NS	1.8+2.1	<.001
N	8	9		7	
<u>PLASMA HEMOGLOBIN (mq/dl)</u>					
MEAN+SD	125+92	120+99	NS	197+390	NS
N	27	25		20	
<u>FIBRIN DEGRADATION PRODUCTS (ug/ml)</u>					
MEAN+SD	853+347	694+365	NS	11+2	<.0001
N	21	24		17	
<u>FIBRINOGEN (mq/dl)</u>					
MEAN+SD	23+14	35+31	NS	127+89	<.0001
N	20	18		18	
<u>PLASMINOGEN (%)</u>					
MEAN+SD	74+17	68+28	NS	56+31	<.01
N	21	23		19	
<u>ANTITHROMBIN III (%)</u>					
MEAN+SD	49+17	45+9	NS	50+35	NS
N	22	25		20	
<u>PROTHROMBIN TIME (seconds)</u>					
MEAN+SD	116+17	120+0	NS	66+48	<.0001
N	18	14		14	
<u>ACTIVATED PARTIAL THROMBOPLASTIN TIME (seconds)</u>					
MEAN+SD	120+0	120+0	NS	109+25	<.02
N	18	14		13	
<u>THROMBIN TIME (seconds)</u>					
MEAN+SD	120+0	120+0	NS	92+46	<.005
N	18	13		11	
<u>FACTOR V CLOTTING PROTEIN (%)</u>					
MEAN+SD	10+0	10+0	NS	12+4	<.01
N	18	15		14	
<u>FACTOR VIII CLOTTING PROTEIN (%)</u>					
MEAN+SD	48+23	35+28	NS	12+5	<.0001
N	17	14		14	

*Analysis of variance: Orth-Evac versus Solcotrans Collection Reservoir

TABLE 5 (cont.)

COLLECTION RESERVOIR:	POSTOPERATIVE DRAINAGE		ANOVA* "p"	LIQUID PRESERVED	SHED VS LIQUID PAIRED T-TEST
	ORTH-EVAC	SOLCOTRANS		BLOOD	"p"
<u>D-DIMER (ug/ml)</u>					
MEAN+SD	>25000+0	>25000+0	NS	1166+1890	<.0001
N	18	20		13	
<u>ANTIPLASMIN (%)</u>					
MEAN+SD	25+12	26+10	NS	46+27	<.001
N	17	16		15	
<u>PLASMIN (%)</u>					
MEAN+SD	90+52	78+39	NS	74+48	NS
N	7	8		7	
<u>THROMBIN (IU/ml)</u>					
MEAN+SD	0.185+0.080	0.205+0.094	NS	0.004+0.004	<.0001
N	21	25		19	
<u>COMPLEMENT C3a dys Arg (ng/ml)</u>					
MEAN+SD	8140+6488	6851+3647	NS	1442+944	<.0001
N	25	21		15	
<u>METHYLMETHACRYLATE MONOMER (ug/ml)</u>					
MEAN+SD	0.0+0.0	0.0+0.0	NS	0.0+0.0	---
N	8	10		6	
<u># FAT PARTICLES <10u/ml</u>					
MEAN+SD	693+585	610+499	NS	31+73	<.01
N	8	9		7	
<u># FAT PARTICLES 10-40u/ml</u>					
MEAN+SD	32+38	23+22	NS	0+0	---
N	8	9		7	
<u># FAT PARTICLES >40u/ml</u>					
MEAN+SD	2+2	1+1	NS	0+0	---
N	8	9		7	

*Analysis of variance: Orth-Evac versus Solcotrans Collection Reservoir

TABLE 6

**IN VITRO MEASUREMENTS OF POSTOPERATIVE ORTHOPEDIC DRAINAGE AND LIQUID PRESERVED BLOOD
PRIOR TO AND FOLLOWING FILTRATION**

COLLECTION RESERVOIR:	40u SCREEN		POLYESTER		ANOVA* "p"	LIQUID-PRESERVED	
	PRE	POST	PRE	POST		PRE	POST
	FILTER		FILTER			170u SCREEN FILTER	
<u>HEMATOCRIT (V%)</u>							
MEAN+SD	19+6	24+9	20+7	22+9	NS	52+27	48+21
N	10	10	7	7		7	7
<u>HEMOGLOBIN (gm/dl)</u>							
MEAN+SD	6.1+2.0	7.8+3.1	6.8+2.6	7.4+2.6	NS	16.5+8.5	15.4+6.8
N	10	10	7	7		7	7
<u>RED BLOOD CELL COUNT (x109/mm3)</u>							
MEAN+SD	2.1+0.7	2.6+1.1	2.1+0.6	2.4+0.9	NS	5.4+2.7	5.0+2.1
N	10	10	7	7		7	7
<u>WHITE BLOOD CELL COUNT (x103/mm3)</u>							
MEAN+SD	6.1+2.2	4.6+2.1	7.1+2.7	1.9+2.2	<0.05	1.8+2.1	1.4+1.8
N	10	10	7	7		7	7
<u>PLASMA HEMOGLOBIN (mg/dl)</u>							
MEAN+SD	125+106	136+124	120+85	115+85	NS	197+390	109+182
N	25	25	27	27		20	19
<u>FIBRIN DEGRADATION PRODUCTS (ug/ml)</u>							
MEAN+SD	748+365	668+388	792+364	853+423	NS	11+2	11+3
N	24	24	21	21		17	18
<u>FIBRINOGEN (mg/dl)</u>							
MEAN+SD	34+30	30+22	24+16	27+21	NS	116+90	138+100
N	19	21	19	18		20	17
<u>PLASMINOGEN (%)</u>							
MEAN+SD	69+20	71+21	73+27	76+38	NS	51+34	56+32
N	24	25	20	22		21	19
<u>ANTITHROMBIN III (%)</u>							
MEAN+SD	45+12	42+12	49+16	42+14	NS	46+36	48+38
N	25	24	22	21		22	19
<u>PROTHROMBIN TIME (seconds)</u>							
MEAN+SD	120+0	108+34	115+19	120+0	NS	66+48	66+47
N	17	17	15	15		14	14
<u>ACTIVATED PARTIAL THROMBOPLASTIN TIME (seconds)</u>							
MEAN+SD	120+0	109+29	120+0	120+0	NS	109+25	103+31
N	17	16	15	15		13	13
<u>THROMBIN TIME (seconds)</u>							
MEAN+SD	120+0	114+23	120+0	120+0	NS	92+46	103+39
N	17	15	14	14		11	12
<u>FACTOR V CLOTTING PROTEIN (%)</u>							
MEAN+SD	10+0	10+0	10+0	10+0	NS	12+4	12+5
N	18	18	15	15		14	14
<u>FACTOR VIII CLOTTING PROTEIN (%)</u>							
MEAN+SD	45+32	44+34	39+17	33+14	NS	12+5	15+8
N	17	15	14	14		14	14

*Analysis of Variance: Pall RC100 Polyester versus Pall 40 Micron Screen Filter Post-Filtration

TABLE 6 (cont.)

COLLECTION RESERVOIR:	40u SCREEN		POLYESTER		ANOVA* "p"	LIQUID-PRESERVED	
	PRE FILTER	POST	PRE FILTER	POST		PRE 170u SCREEN FILTER	POST
<u>D-DIMER (ug/ml, X103)</u>							
MEAN+SD	>25+0	>25+0	>25+0	>25+0	NS	0.66+0.49	0.52+0.39
N	21	22	17	17		13	11
<u>ANTIPLASMIN (%)</u>							
MEAN+SD	28+12	33+16	23+7	23+6	NS	42+28	45+27
N	20	18	13	12		19	15
<u>PLASMIN (%)</u>							
MEAN+SD	72+39	63+21	97+49	103+41	NS	58+52	68+40
N	8	8	7	7		9	8
<u>THROMBIN (IU/ml)</u>							
MEAN+SD	0.17+0.08	0.17+0.08	0.22+0.09	0.21+0.10	NS	0.004+0.004	0.003+0.002
N	24	22	22	21		21	19
<u>COMPLEMENT C3a dys Arg (ng/ml)</u>							
MEAN+SD	7051+3193	8188+4636	8005+6816	9252+6345	NS	1442+944	2000+1289
N	22	25	24	25		15	17
<u>METHYLMETHACRYLATE MONOMER (ug/ml)</u>							
MEAN+SD	0.0+0.0	0.0+0.0	0.0+0.0	0.0+0.0	NS	0.0+0.0	0.0+0.0
N	9	9	9	9		6	6
<u># FAT PARTICLES <10u/ml</u>							
MEAN+SD	576+451	431+546	754+637	321+246	NS	31+73	15+35
N	10	10	7	7		7	7
<u># FAT PARTICLES 10-40u/ml</u>							
MEAN+SD	25+23	14+17	30+39	5+9	NS	0+0	0+0
N	10	10	7	7		7	7
<u># FAT PARTICLES >40u/ml</u>							
MEAN+SD	2+2	1+2	1+2	0+1	NS	0+0	0+0
N	10	10	7	7		7	7

*Analysis of Variance: Pall RC100 Polyester versus Pall 40 Micron Screen Filter Post Filtration

TABLE 7

HEMATOLOGIC AND CLOTTING PROTEIN MEASUREMENTS IN PATIENTS PRIOR TO AND FOLLOWING THE REINFUSION OF
POSTOPERATIVE SHED BLOOD COLLECTED INTO 2 DIFFERENT RESERVOIRS AND LIQUID PRESERVED BLOOD

	ORTH-EVAC COLLECTED				SOLCOTRANS-COLLECTED				LIQUID PRESERVED			
	POSTOPERATIVE DRAINAGE				POSTOPERATIVE DRAINAGE				BLOOD (CONTROL)			
	PRE OP	POST-OP PRE TXN	1HR	24HR	PRE OP	POST-OP PRE TXN	1HR	24HR	PRE OP	POST-OP PRE TXN	1HR	24HR
<u>HEMATOCRIT (V%)</u>												
MEAN±SD	38±5	32±4	32±4	32±3	37±3	33±2	33±3	33±1	36±5	31±3	31±2	31±1
N	10	8	8	5	8	9	9	6	12	7	7	5
<u>HEMOGLOBIN (gm/dl)</u>												
MEAN±SD	12.3±1.7	10.6±1.3	10.8±1.2	11.1±1.3	11.8±1.0	10.5±0.8	10.6±0.8	10.8±0.5	11.6±1.7	10.0±0.8	10.0±1.5	10.1±0.4
N	10	8	8	5	8	9	9	6	12	7	7	5
<u>RED BLOOD CELL COUNT (x10⁹/mm³)</u>												
MEAN±SD	4.2±0.6	3.6±0.4	3.6±0.4	3.7±0.3	3.9±0.3	3.5±0.3	3.5±0.3	3.6±0.1	3.8±0.5	3.3±0.3	3.4±0.4	3.2±0.2
N	10	8	8	5	8	9	9	6	12	7	7	5
<u>WHITE BLOOD CELL COUNT (x10³/mm³)</u>												
MEAN±SD	6.8±1.9	12.0±3.3	14.3±3.5	12.3±1.5	5.3±1.2	11.7±2.2	12.2±2.9	10.8±2.9	6.3±1.8	11.2±2.4	11.7±2.2	10.8±3.3
N	10	8	8	5	8	9	9	6	12	7	7	5
<u>PLATELET COUNT (x10⁵/mm³)</u>												
MEAN±SD	294±75	241±49	227±52	238±34	262±68	223±65	194±64	195±42	257±63	200±61	217±82	181±20
N	10	8	8	5	8	9	9	6	12	7	7	5
<u>MEAN PLATELET VOLUME (x10⁵/mm³)</u>												
MEAN±SD	8.6±1.0	8.6±1.0	8.7±1.0	7.7±0.5	9.1±1.2	9.1±1.0	9.3±1.2	9.1±1.1	8.9±0.9	9.0±0.7	9.6±1.3	8.4±0.5
N	10	8	8	5	8	9	9	6	12	7	7	5
<u>PLASMA HEMOGLOBIN (mg/dl)</u>												
MEAN±SD	8.0±10.2	5.4±4.8	5.6±4.7	4.6±5.4	6.9±8.7	8.6±15.5	7.2±6.6	4.4±3.4	8.5±8.3	7.7±11.2	7.3±9.5	4.8±6.4
N	25	25	25	21	29	29	29	27	27	20	22	20
<u>FIBRIN DEGRADATION PRODUCTS (ug/ml)</u>												
MEAN±SD	12±7	30±35	114±143	20±16	11±3	26±21	74±66	20±17	11±3	23±33	27±25	20±12
N	21	19	20	21	24	24	23	23	20	20	19	17
<u>D-DIMER (ug/ml, x10⁻³)</u>												
MEAN±SD	1.0±0.7	7.9±7.2	19.0±6.9	4.9±5.2	1.0±0.9	8.7±5.3	20.4±6.4	4.4±2.6	0.6±0.2	4.6±5.7	5.8±4.3	2.4±1.5
N	14	17	18	13	21	20	22	19	16	18	16	14
<u>FIBRINOGEN (mg/dl)</u>												
MEAN±SD	416±112	310±102	263±66	440±160	350±95	286±63	289±88	433±122	341±91	307±101	288±110	433±132
N	22	21	19	21	24	22	22	21	20	20	20	16

TABLE 7 (cont..)

ORTH-EVAC COLLECTED				SOLCOTRANS-COLLECTED				LIQUID PRESERVED			
POSTOPERATIVE DRAINAGE				POSTOPERATIVE DRAINAGE				BLOOD (CONTROL)			
PRE	POST-OP	PRE	POST-OP	PRE	POST-OP	PRE	POST-OP	PRE	POST-OP	PRE	POST-OP
OP	PRE	OP	PRE	OP	PRE	OP	PRE	OP	PRE	OP	PRE
24HR	1HR	24HR	1HR	24HR	1HR	24HR	1HR	24HR	1HR	24HR	1HR
<u>PLASMINOGEN (%)</u>											
MEAN+SD	105+7	91+15	104+29	92+23	104+14	97+18	117+20	83+13	105+9	90+18	93+13
N	22	21	22	20	22	24	22	20	20	20	19
<u>ANTITHROMBIN III (%)</u>											
MEAN+SD	105+16	90+17	91+21	91+18	104+15	90+13	90+13	86+15	110+11	91+14	92+17
N	21	21	21	20	26	25	25	23	20	20	20
<u>PROTHROMBIN TIME (seconds)[#]</u>											
MEAN+SD	10.8+0.6	11.7+0.9	12.0+1.5	11.8+1.3	11.1+1.2	11.5+0.9	11.6+1.0	11.7+0.8	11.0+0.6	11.9+1.4	13.5+3.5
N	18	17	16	18	15	14	13	15	15	14	15
<u>ACTIVATED PARTIAL THROMBOPLASTIN TIME (seconds)[#]</u>											
MEAN+SD	31.1+3.6	32.4+4.8	31.4+6.1	36.0+6.5	31.6+5.2	30.3+3.8	29.9+3.6	34.3+3.9	35.3+5.4	33.6+4.5	34.8+7.2
N	18	17	16	17	14	14	14	14	15	14	14
<u>THROMBIN TIME (seconds)[#]</u>											
MEAN+SD	10.8+0.6	12.7+2.3	12.8+4.4	10.1+1.3	10.9+2.2	12.5+2.7	12.0+2.3	10.6+1.7	10.5+1.7	10.8+2.1	11.3+2.2
N	18	15	15	18	13	12	11	14	14	12	13
<u>FACTOR V CLOTTING PROTEIN (%)</u>											
MEAN+SD	83+26	47+16	48+24	62+24	88+25	52+17	47+5	57+11	74+20	46+16	38+17
N	17	17	17	17	14	14	15	14	15	15	15
<u>FACTOR VIII CLOTTING PROTEIN (%)</u>											
MEAN+SD	115+26	117+51	125+58	126+38	97+25	119+57	120+47	102+28	92+32	101+41	96+42
N	18	16	17	18	14	14	13	13	14	15	15
<u>ANTIPLASMIN (%)</u>											
MEAN+SD	78+10	71+10	70+10	75+16	83+14	72+13	69+18	81+16	83+9	77+10	76+12
N	15	16	17	19	16	15	16	16	17	16	17
<u>PLASMIN (%)</u>											
MEAN+SD	56+15	72+32	73+41	71+50	56+15	69+36	59+23	58+19	58+15	60+18	58+11
N	7	7	7	7	7	8	7	7	9	9	9
<u>THROMBIN (IU/mL, X103)</u>											
MEAN+SD	3+3	2+2	3+1	5+8	4+7	3+3	5+5	6+10	5+7	2+1	2+1
N	18	20	19	19	24	25	24	24	21	20	20

[#]Excluding 8 patients with abnormal PT, aPTT and/or TT results: 4 patients who received liquid preserved red blood cells only and 4 patients who received shed blood and liquid preserved red blood cells.

TABLE 7 (cont.)

ORTH-EVAC COLLECTED				SOLCOTRANS-COLLECTED				LIQUID PRESERVED			
POSTOPERATIVE DRAINAGE				POSTOPERATIVE DRAINAGE				BLOOD (CONTROL)			
PRE	POST-OP	PRE	24HR	PRE	POST-OP	PRE	24HR	PRE	POST-OP	PRE	24HR
OP	PRE	TXN	1HR	OP	PRE	TXN	1HR	OP	PRE	TXN	1HR
<u>COMPLEMENT C3a dys Arg (ng/ml)</u>											
MEAN+SD	440+223	591+584	605+510	504+314	690+876	890+1335	837+1108	410+260	413+303	429+295	471+201
N	22	27	21	22	22	20	20	15	15	16	16
<u>METHYLMETHACRYLATE MONOMER (ug/ml)</u>											
MEAN+SD	---	0.0+0.0	0.0+0.0	---	0.0+0.0	0.0+0.0	0.0+0.0	---	0.0+0.0	0.0+0.0	0.0+0.0
N	---	9	9	---	10	10	6	---	6	6	6
<u># FAT PARTICLES <10u/ml</u>											
MEAN+SD	4.1+8.7	7.3+18.8	3.6+9.6	0.6+1.3	1.1+2.5	4.4+11.5	5.7+12.2	0.6+1.5	0.0+0.0	1.1+1.7	0.0+0.0
N	10	8	8	8	9	9	6	10	6	7	6
<u># FAT PARTICLES 10-40u/ml</u>											
MEAN+SD	3.0+9.0	3.0+7.9	3.1+8.3	0.0+0.0	0.4+1.3	2.1+6.0	3.3+7.5	0.1+0.3	0.0+0.0	0.0+0.0	0.0+0.0
N	10	8	8	8	9	9	6	10	6	7	6
<u># FAT PARTICLES >40u/ml</u>											
MEAN+SD	2.3+3.9	0.3+0.5	1.7+2.4	0.0+0.0	0.1+0.3	0.0+0.0	0.0+0.0	0.0+0.0	0.0+0.0	0.0+0.0	0.0+0.0
N	4	3	3	8	9	9	6	10	6	7	6

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